## REMARKS

### I. Introduction

The Final Office Action mailed March 23, 2010, has been carefully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

### II. Status of Claims

Claims 1-38 are pending. Claims 10-19 and 21-38 have been withdrawn from consideration by the Examiner as being drawn to non-elected inventions. Claim 1 has been amended. Support for the amendment is found, *inter alia*, on page 5, last full paragraph, and page 6, first paragraph.

### III. Summary of the Office Action

In the office action, the Examiner rejects

1) claims 1-9 under 35 U.S.C. § 112, first paragraph, as lacking enablement for the full scope of the claims;

2) claims 1-9 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps;

3) claims 1-5 and 20 under 35 U.S.C. § 102(b) as being anticipated by Elbein (U.S. Patent No. 5,021,427); and

4) claims 1-9 and 20 under 35 U.S.C. § 103(a) as being obvious over each of Collins et al. (WO 99/34810), Abidi (Journal of Chromatography A 935:173-

201 (2001)) and Khwaja et al. (U.S. Patent No. 6,113,907), in view of Elbein supported by Karuza et al. (Journal of Pharmaceutical and Biomedical Analysis 15:419-422, 1996).

## IV. Arguments

Applicants respectfully traverse the rejections for the following reasons:

### A. The Claims Are Enabled

Claims 1-9 stand rejected as lacking enablement for the full scope of the claims. The Examiner alleges that the claims are enabled "for herbal medicines which comprise phytochemicals selected from the group consisting of that which is exemplified in the claims," but "does not reasonable provide enablement for extracting the claimed phytochemicals from any herbal medicine." Office Action at 3. Applicants have amended the claim 1 to recite that "the herbal medicine comprises phytochemicals selected from the group consisting of pyrrolidine, piperidine, pyrrolizidine, indolizidine, tropane, and nortropane alkaloids." Therefore, as noted by the Examiner the claims are now enabled. Accordingly, Applicants respectfully request withdrawal of the rejection.

### B. The Claims Are Not Indefinite

Claims 1-9 stand rejected as being indefinite. The Examiner alleges that the claims omitted the essential "step which correlates the characterizing to the quality of an herbal medicine." Applicants respectfully traverse the rejection.

Applicants respectfully note that one skilled in the art would know how to monitor the

quality of the herbal medicine from the steps recited. This is clear especially from the disclosure of the specification on page 5, first paragraph. Many methods or steps of the prior art can be used to monitor quality; and one skilled in the art would be familiar with and be able to utilize those methods to determine the quality of the herbal medicine. Thus, the specific steps required to correlate the quality of the herbal medicine from the characterization step is not essential to the present invention because those skilled in the art would know how to accomplish the correlation. Therefore, the claims are not indefinite.

The Examiner has cited MPEP 2172.01 to support his assertion that he claims are indefinite; however, the cases cited in that section (*In re Venezia*, 189 USPQ 149 (CCPA 1976) and *In re Collier*, 158 USPQ 266 (CCPA 1968)) are not applicable here. In *Venezia*, the court actually reversed the Board's finding of indefiniteness. Thus, that case holds contrary to the Examiner's position.

In *Collier*, the court found indefiniteness because "the claim does not positively recite structural relationships of the two elements" recited in the claim. That is not the case here. The present claims recite three steps (a, b, and c). Step b acts on the herbal medicine provided in step a; and step c acts on the polar phytochemicals extracted in step b. Thus, because the present claims contain relationships between the steps, *Collier* does not apply here.

**C. The Claims Are Not Anticipated**

Claims 1-5 and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Elbein. Applicants respectfully traverse the rejection.

To anticipate a claim, the reference must teach every element of the claim. *See* MPEP § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found,

either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that Elbein does not disclose every element of the claimed invention. In particular, the reference fails to disclose "a herbal medicine" or a method for monitoring the quality of that herbal medicine. The Examiner is referred to page 6 the specification which defines the term "herbal medicine" as follows:

> The term herbal medicine is used herein to define a pharmaceutical composition in which at least one active principle is not chemically synthesized and is a phytochemical constituent of a plant. In most cases, this non-synthetic active principle is not purified, but present together with other phytochemicals with which it is associated in the source plant.

Elbein fails to disclose "an herbal medicine" as defined by the present invention because it fails to disclose "a pharmaceutical composition." Elbein discloses purification of Australine, an alkaloid, from *Castanospermum australe*. *See* Elbein, column 5, lines 13-30. There is no disclosure that the *C. australe* is a pharmaceutical composition. In fact, Elbein discloses the purified Australine as an antiviral or antiretroviral pharmaceutical, not *C. australe* itself. See Elbein, column 2, lines 59-68. There is no disclosure that *C. australe* can be effectively used as a pharmaceutical composition.

Additionally, in the present invention, the phytochemical is extracted from the pharmaceutical composition (herbal medicine); in Elbein, the Australine (the pharmaceutical composition) is extracted from *C. australe*. Thus, Elbein provides a method for making the pharmaceutical composition (Australine) from *C. australe*, but does not provide a method for monitoring the quality of a herbal medicine. The Examiner is directed to page 7 of the present specification where quality is defined as follows:

> In this context, the term quality is used to define the overall fitness of the herbal medicament for its intended use, and may include for example the presence of one or more bioactive principles (at an appropriate concentration), the presence of one or more bioactive markers, a phytochemical profile which indicates the use of a particular source, condition, purity and an acceptable or unacceptable degree of contamination with undesirable supplements and/or contaminants.

Elbein merely purifies Australine. But the reference does not disclose any quality monitoring as defined in the present specification. It fails to mention any "fitness of the herbal medicament for its intended use." Elbein merely purifies and use Australine in a pharmaceutical composition without disclosing any quality monitoring method.

Therefore, for the reasons noted, Elbein does not anticipate the present invention within the meaning of 35 U.S.C. § 102. Accordingly, Applicants respectfully request withdrawal of the rejection.

**D. The Claims Are Not Obvious**

Claims 1-9 and 20 stand rejected as being obvious over the combination of each of Collins et al. (WO 99/34810), Abidi (Journal of Chromatography A 935:173-201 (2001)) and

Khwaja et al. (U.S. Patent No. 6,113,907), in view of Elbein supported by Karuza et al. (Journal of Pharmaceutical and Biomedical Analysis 15:419-422, 1996).

Applicants respectfully submit that Collins et al., Abidi, and Khwaja et al. do not disclose every element of the claimed invention. Collins et al. fails to disclose the extraction of polar phytochemicals. That reference discloses the isolation of non-polar (not polar) extractives. The processes and methods described in this document are explicitly stated to effect the recovery of various non-polar compounds at high yield, purity and unaltered form for use in various forms of industry. *See, e.g.,* page 5, lines 7-8. Specifically, Collins et al. disclose the use of an aliphatic-substituted polysaccharide gel matrix in a process of hydrophobic interaction chromatography "for the isolation, recovery and purification of non-polar extractives..." See, e.g., Abstract (emphasis added). There is no teaching or suggestion that the processes be adapted and applied to the quality control of herbal medicines, or of the characterization of polar extracts for this (or any other) purpose. Accordingly, Collins et al. disclose extraction of a class of compounds (non-polar compounds) that is completely inapposite to that of the present invention (polar compounds). In doing so, Collins et al. actually teach away from the present invention, which extracts for polar compounds rather than the non-polar compounds of Collins et al.

Abidi also fails to disclose the extraction of polar phytochemicals. That reference discloses the analysis of a particular class (sterols) of non-polar (not polar) extracts. The processes described by Abidi explicitly addresses "the increasing public interest in the cholesterol-reducing capacity of phytosterols" and the "impetus to review existing chromatographic methods" generated thereby (see page 176, closing paragraph of section 1). The extracts analyzed are non-polar (see section 2.1 at page 177), a corollary of the non-polar nature of the analytes of interest (sterols). There is no teaching or suggestion in Abidi that his

processes be adapted and applied to the quality control of herbal medicines, or of the characterization of polar extracts for this (or any other) purpose. Indeed, the entire teaching of Abidi is narrowly confined to the analysis of non-polar sterol components (principally those present in vegetable oils). Accordingly, like Collins et al., Abidi discloses extraction of a class of compounds that is completely inapposite to that of the present invention. In doing so, Abidi actually teaches away from the present invention, which extracts for polar compounds rather than the non-polar compounds of Abidi.

Khwaja et al. also fail to disclose the extraction of polar phytochemicals. The methods described in this reference do not profile polar phytochemicals of the classes claimed. Although the process described partitions them into a final water fraction, the patent refers to this fraction as containing sugars, not phytochemicals. The focus is on a fingerprint of flavonoids/phenolics that are the well known components of St John's Wort and are quantified by most analytical labs using standard methods. See, e.g., column 20, lines 45-54. The phenolic profiles shown are typical anti-oxidant profiles used by many laboratories. Khwaja et al. simply describes a method which purifies these components to a higher degree. The alkaloid fraction described in Khwaja et al. will contain classic non-polar alkaloids extractable into non-polar solvents but not more polar alkaloids/amines such as iminosugars. In contrast, the claimed method characterizes the specified polar phytochemicals. The method of Khwaja et al. does not separate polar and non polar alkaloids. It is therefore respectfully submitted that Khwaja et al. do not disclose the quality monitoring methods of the present invention.

The Examiner relies on Elbein to disclose "extracting seed material with methanol to produce a polar phytochemical" (Office Action, page 8), and on Karuza et al. to disclose "analyzing the quality and extracts of herbal medicines using chromatography methods" (Office

Action, page 9). However, because Elbein and Karuza et al. fail to cure the deficiencies of Collins et al., Abidi, or Khwaja et al., their combination still cannot render the present invention obvious within the meaning of 35 U.S.C. § 103.

Additionally, one skilled in the art would not combine the teaching of Elbein with those of Collins et al., Abidi, or Khwaja et al. As previously mentioned Collins et al. and Abidi disclose extraction of non-polar compounds. The Examiner has alleged that Elbein discloses the production of polar phytochemicals. One of ordinary skill in the art would not have used the method to produce polar compounds of Elbein to extract the non-polar compounds of Collins et al. or Abidi.

With regard to Khwaja et al., as mentioned above, that reference discloses the purification of alkaloids (polar and non-polar) from St. John's Wort. One of ordinary skill in the art would not have used a method to produce polar compounds of Elbein to purify the alkaloids of Khwaja et al., because to do so would result in the elimination of non-polar alkaloids which is a desirable component of St. John's Wort. One of ordinary skill in the art would not have wanted to eliminate a desired component of Khwaja et al.

Therefore, for the reasons noted, the present invention is not obvious over the cited references, taken alone or in combination. Accordingly, Applicants respectfully request withdrawal of the rejection.

## V. Conclusion

Applicants have responded to the Final Office Action mailed March 23, 2010. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (133604-00101). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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